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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3002917375
Facility ID:221030
Inspection ID #2210300005

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

03-BLT-21

July 17, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Stephen Y. Karsh, Lead Interpreting Physician
Healthsouth Diagnostic Center of Frederick
110 Baughman's Lane
Suite 120
Frederick, Maryland 21702

Dear Dr. Karsh:

We are writing to you because on June 16, 2003, a representative of the State of Maryland, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. The violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* which was issued to your facility at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility. The violations are again identified below.

- **Level 1:** Your facility failed to document that a weekly phantom quality control test was performed on the weeks beginning 05/19/2002, 8/18/2002, 10/06/2002, 10/13/2002, and 10/20/2002 **[21 CFR 900.12(e)(2)]**.

- **Level 1:** Your facility failed to document that processor quality control was performed for the processor identified in your inspection report as processor #1, Kodak, on 09/5/02, 9/6/02, 9/18/02, 9/19/02, 9/20/02, 9/23/02, 9/24/02, 9/25/02, 9/26/02, 9/27/02, 9/30/02, 10/7/02, 10/8/02, 10/9/02, 10/10/02, 10/11/02, 10/14/02, 10/15/02, 10/16/02, 10/17/02, 10/18/02, 10/21/02, 10/22/02, 10/23/02, 10/24/02, 10/25/02, 10/28/02, and 10/29/2002 **[21 CFR 900.12(e)(1)]**.

- **Level 2:** Your facility's processor quality control testing exceeded preset limits on 8/27/2002 and no corrective action was documented **[21 CFR 900.12(e)(8)].**

- **Level 2:** Your facility failed to perform an annual medical audit and outcome analysis for each individual radiologist and for your facility as a whole **[21 CFR 900.12(f)(1)].**

- **Level 2:** Your facility failed to perform phantom quality control testing at the clinical setting used for an average 4.2 cm breast 50/50 composition **[21 CFR 900.12(e)(2)(i)].**

- **Level 2:** Your facility failed to get biopsy results for biopsies recommended by your interpreting radiologists **[21 CFR 900.12(f)(1)].**

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional regulatory actions. These actions include, but are not limited to, requiring your facility to undergo an additional Mammography Review, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA Standards, or suspension or revocation of your facility's FDA certificate. See 42 U.S.C. 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. The specific steps you have taken, or will take, to **correct** all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. Each step your facility is taking to **prevent the recurrence** of similar violations, including projected time frames for implementing those steps; and

3. Sample records that demonstrate proper record keeping procedures (**Note: Patient names or identification should be deleted from any copies submitted**).

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Elizabeth A. Laudig, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Lee Bowers
Director, Baltimore District